

## § 610.50

Administration's regulations on conditions of Medicare participation for hospitals (42 CFR part 482) are required to take appropriate action in accordance with paragraphs (b) and (c) of this section when a recipient has received Whole Blood or blood components from a donor determined to be unsuitable when tested for human immunodeficiency virus (HIV) infection in accordance with § 610.45 and the results of the additional tests as provided for in § 610.46(b) are positive.

(b) *Notification of recipients of prior transfusion.* If the transfusion service has administered Whole Blood or blood components as described in paragraph (a) of this section, the transfusion service shall notify the recipient's attending physician (physician of record) and ask him or her to inform the recipient of the need for HIV testing and counseling. If the physician is unavailable or declines to notify the recipient, the transfusion service shall notify the recipient and inform the recipient of the need for HIV testing and counseling. The notification process shall include a minimum of three attempts to notify the recipient and be completed within a maximum 8 weeks of receipt of the result of the licensed, more specific test for HIV. The transfusion service is responsible for notification, including basic explanations to the recipient and referral for counseling, and shall document the notification or attempts to notify the attending physician or the recipient, pursuant to § 606.160 of this chapter.

(c) *Notification to legal representative or relative.* If the transfusion recipient has been adjudged incompetent by a State court, the transfusion service or physician must notify a legal representative designated in accordance with State law. If the transfusion recipient is competent, but State law permits a legal representative or relative to receive the information on the recipient's behalf, the transfusion service or physician must notify the recipient or his or her legal representative or relative. If the transfusion recipient is deceased, the transfusion service or physician must continue the notification process and inform the deceased recipient's legal representative or relative. Reasons for notifying the recipient's

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ent's relative or legal representative on his or her behalf shall be documented pursuant to § 606.160 of this chapter.

[61 FR 47423, Sept. 9, 1996]

### Subpart F—Dating Period Limitations

#### § 610.50 Date of manufacture.

The date of manufacture shall be determined as follows:

(a) For products for which an official standard of potency is prescribed in either § 610.20 or § 610.21, or which are subject to official potency tests, the date of initiation by the manufacturer of the last valid potency test.

(b) For products that are not subject to official potency tests, (1) the date of removal from animals, (2) the date of extraction, (3) the date of solution, (4) the date of cessation of growth, or (5) the date of final sterile filtration of a bulk solution, whichever is applicable.

[38 FR 32056, Nov. 20, 1973, as amended at 42 FR 27582, May 31, 1977]

#### § 610.53 Dating periods for licensed biological products.

(a) *General.* The minimum dating periods in paragraph (c) of this section are based on data relating to usage, clinical experience, or laboratory tests that establish the reasonable period beyond which the product cannot be expected to yield its specific results and retain its safety, purity, and potency, provided the product is maintained at the recommended temperatures. The standards prescribed by the regulations in this subchapter are designed to ensure the continued safety, purity, and potency of the products and are based on the dating periods set forth in paragraph (c) of this section. Package labels for each product shall recommend storage at the stated temperatures.

(b) *When the dating period begins.* The dating period for a product shall begin on the date of manufacture, as prescribed in § 610.50. The dating period for a combination of two or more products shall be no longer than the dating period of the component with the shortest dating period.

(c) *Table of dating periods.* In using the table in this paragraph, a product